

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: West, *et al.*

Confirmation No.: 4414

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Group Art Unit: 1775

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Examiner: Bowers, Nathan A.

For: **MICROFLUIDIC INTEGRATED MICROARRAYS FOR
BIOLOGICAL DETECTION**

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Sir:

**APPELLANTS' PETITION FOR REHEARING
PURSUANT TO 37 C.F.R. § 41.52**

Appellants petition the Board for rehearing in the present appeal pursuant to 37 C.F.R. § 41.52. Because this petition is being filed within two months of the Board's March 1, 2011 decision, the petition is timely under 37 C.F.R. § 41.52.

I. BACKGROUND

Appellants' invention is directed to, *inter alia*, microfluidic chips having microarrays disposed within microchannels having depths of from about 1 to about 10 micrometers. These chips are useful in the analysis and identification of biological organisms and biomarkers, including organisms that may be used as bioweapons.

The pending claims in appellants' application stand finally rejected. To support these rejections, the examiner combined (1) prior art that teaches that channels having depths of less than 15 micrometers "cause[] problems" and are "difficult to fill" with (2) prior art that teaches channels having depths of less than 10 microns. Appellants also presented evidence that their invention achieves results nearly 10 times faster than the very art on which the examiner relied. The examiner finally rejected appellants' claims despite this evidence.

On March 1, 2011, the Board affirmed the examiner's final rejection of appellants' independent claim 1 and its related dependent claims. But instead of adopting the examiner's prior art interpretations as its own, the Board sustained the rejections of appellants' claims

based on (1) an interpretation of the prior art the examiner had never advanced during prosecution and (2) a failure to fully consider appellants' arguments concerning the prior art. The Board also rejected appellants' evidence of superior performance, failing to recognize that appellants' evidence reflected that the claimed invention exhibited superiority over existing alternative products and a 10-fold performance advantage over the cited prior art. This misapprehension of the issues and evidence warrants rehearing of the case.

II. ARGUMENT

A. Summary of Argument

Because the Board's decision rests on misapprehending the arguments and evidence presented on appeal, the Board should withdraw its decision and rehear this appeal.

First, the Board misstated the questions presented on appeal. More specifically, the Board's Opinion ("Op.") framed the issues presented in this appeal as whether the examiner had "reversibly erred" in reaching his findings (Op. at 4). But because that is not the actual question presented here, the Board's statement of the issues is incorrect.

Second, the Board rested its decision on an interpretation of the prior art that the examiner had never advanced during prosecution (Op. at 5-6), and appellants have thus had no opportunity to respond to this interpretation. By relying on a new interpretation of the prior art, the Board has advanced a new ground of rejection and also impliedly conceded that the examiner's previous findings were insufficient to sustain the final rejections of appellants' claims.

The Board also found that appellants' objective evidence of nonobviousness did not properly compare the claimed invention with the prior art (Op. at 8-9). The Board's conclusion, however, misapprehended appellants' submissions, as appellants' evidence of record establishes the superiority of the claimed invention over existing alternative devices and over the cited prior art. Because the Board's decision was based on misapprehending appellants' arguments and appellants' evidence, the Board should rehear this case.

B. The Board Mis-Framed the Issues on Appeal and Misapprehended Appellants' Arguments

The Board should reconsider its March 1, 2011 decision because (1) the decision rested on a misstatement of the issues presented on appeal, and (2) the decision failed to fully consider appellants' arguments concerning the prior art.

1. The Board's Characterization of the Issues on Appeal Misapprehends the Actual Questions Presented

In its decision, the Board framed the question before it as whether the examiner had “reversibly erred” in finding that the cited prior art suggested every limitation of appellants’ independent claim 1 (Op. at 4). This characterization of the issues on appeal misapprehends the actual questions before the Board.

While the Board framed the question before it as simply reviewing the examiner’s findings for reversible error. But the question on appeal is not whether the examiner committed reversible error. Instead, as the Federal Circuit explained in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (citations omitted):

[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.

By statute, the Board is to “review adverse decisions of examiners upon applications for patents.” 35 U.S.C. § 6(b). Thus, before the Board even need address appellants’ position on appeal – the issue on appeal is whether, under the Board’s own statutory review, the examiner established a *prima facie* case of unpatentability for every element of independent claim 1 before turning to appellants’ position on appeal, as “without more[,] [appellants] are entitled to grant of the patent.” 977 F.2d at 1445. By characterizing the issue on appeal as whether the examiner had committed reversible error (and thus giving undue deference to the examiner) instead of whether the examiner had established a *prima facie* case of obviousness under the Board’s statutory standard of review, the Board gave improper deference to the examiner and mischaracterized the issues presented in this appeal.

In essence, by adopting a “reversible error” standard of review the Board necessarily assumes the examiner’s statement of rejection as it appears in the Examiner’s Answer is correct. But such a presumption of correctness is inconsistent with appellants’ statutory entitlement to a patent set forth in the preamble of 35 U.S.C. § 102, i.e., “[a] person shall be

entitled to a patent unless –.” The standard of review set forth in *In re Oetiker*, *supra*, is consistent with the preamble of Section 102, as it rightfully places the burden on the examiner to initially establish a so-called *prima facie* case of unpatentability before applicant is required to go forward.

In this case, there is no indication in the opinion that the Board initially reviewed the examiner’s statement of rejection and independently determined whether the examiner’s facts and reasoning were sufficient to establish *prima facie* obviousness and shift the burden to appellants to go forward. Instead, it appears that the Board reviewed the examiner’s rejection for “reversible error,” thereby improperly shifting the initial burden to appellants.

In addition, the Board’s description of its resolution of the issue on appeal is also incorrect. Although the Board stated that it had decided “in the negative” the question whether the examiner had reversibly erred “in finding that the teachings of Mathies, McNeely and Quake, as a whole, would have suggested using a microchannel depth ‘from about 1 micron to about 10 microns’ as required by claim 1” (Op. at 4), the Board’s statement is not correct. While the Board nominally “affirmed” the obviousness rejections of appellants’ claims, the Board did so (Op. at 5) based on statements in the McNeely reference concerning “backfilling,” on which statements the examiner never relied during prosecution. Thus, the fact that the Board could reject appellants’ claims only after interpreting the prior art in a way that differed from the examiner demonstrates reveals the Board’s conclusion that the examiner’s findings could *not* support a *prima facie* case of obviousness. The Board’s misapprehension of the issue on appeal warrants rehearing of the case.

2. The Board’s Decision Relies on the Examiner’s Incomplete Characterization of the McNeely Reference

In its decision, the Board rejected appellants’ arguments that McNeely’s statements that (1) chamber heights are to be “at least 15 μm ,” (2) that shallow channels are “difficult to fill,” and (3) that “reducing the volume by reducing the chamber height causes problems if the height goes below about a certain height” (McNeely at [0084]) were a teaching away from appellants’ claimed chambers having a depth of from 1-10 microns (Op. at 6). The Board, however, misapprehended appellants’ arguments and failed to acknowledge the examiner’s failure to properly quote the McNeely reference.

In their opening brief (“Br.”), appellants argued that the plain language of McNeely paragraph [0084] constituted a teaching away from the claimed channels having a depth of

from about 1 to about 10 micrometers (Br. at 7-8). In his answer (“Answer”) to appellants’ opening brief, the examiner stated that

“McNeely expresses an interest in even smaller microarray channels/chambers in paragraph [0084] (*‘while it is desirable to have a small reaction chamber volume . . .’*), but cannot obtain smaller sizes due to his reliance on providing a gasket between the base substrate and coverslip” (Answer at 26, emphasis added)

The examiner, however, failed to fully quote McNeely paragraph [0084] and in fact omitted language favorable to appellants’ position. Despite the examiner’s plainly incomplete representation of the McNeely reference, the Board nonetheless approved of the examiner’s interpretation of McNeely (Op. at 6). The Board’s reliance on the examiner’s incomplete findings was in error.

Properly quoted, McNeely paragraph [0084] actually states:

“The height of [the] reaction chamber [] is defined by the thickness of [the] gasket . . . In the preferred embodiment of the invention, [the gasket] has a thickness of at least about 15 μm [.] As gasket thickness is decreased, roughness of the slide surface and lower surface of the interface device, and nonuniformity of the gasket may become problematic. Moreover, if the gasket thickness is decreased further, the chamber may become too difficult to fill. Therefore, while it is desirable to have a small reaction chamber volume, it appears that reducing the volume by reducing the chamber height causes problems if the height goes below about a certain height” (McNeely at [0084]) (emphasis added).

The language emphasized above highlights that reducing the chamber height results in the chamber *“becoming too difficult to fill”* and that *“reducing the chamber height causes problems if the height goes below about a certain height”* (McNeely at [0084]) (emphasis added). That reducing the chamber height renders the chamber “difficult to fill” and “causes problems” is a clear teaching away from chambers having a height of less than the 15 microns, and neither the examiner nor the Board ever confronted this critical aspect of McNeely paragraph [0084]. See *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (reversing finding of obviousness where district court erred by “considering the references in less than their entireties”).

C. The Board Has Asserted a New Ground of Rejection to Which Appellants Must Have a Chance to Respond

Advancing an interpretation of the prior art on which the examiner had never relied, the Board found that appellants' independent claim 1 was *prima facie* obvious over the cited art (Op. at 5-6). Because the Board has relied on a new interpretation of the prior art to which appellants have not had a chance to respond, the examiner's rejections can not be affirmed and should in fact be reversed.

1. The Board's Decision Rests on a New Ground of Rejection

To counter McNeely's statements that shallow channels "cause[] problems" and are "difficult to fill" (McNeely at [0084]), the Board suggests that McNeely "provides an embodiment using backfill in the microchannel to achieve the smaller microchannel depths and volumes" (Op. at 5-6, citing McNeely at [0137]). But the examiner never relied on this interpretation of McNeely, and the Board's reliance on an interpretation that differs from the examiner's demonstrates the Board's implicit conclusion that the examiner's findings could *not* sustain the final rejections of appellants' claims. Appellants, however, have not had the opportunity to respond to this new interpretation of McNeely and should be afforded an opportunity to do so. 37 C.F.R. § 41.50(b). Accordingly, because the Board has asserted a new ground of rejection on appeal, appellants should have the opportunity to respond.

2. The Board's New Ground of Rejection Does Not Support *Prima Facie* Obviousness

In any event, the Board's new reliance on paragraph [0137] of McNeely to sustain the rejections misapprehends appellants' arguments concerning the McNeely reference. To the extent McNeely paragraph [0137] provides disclosure concerning backfilling channels, the paragraph teaches only that backfilling "may form a smoother and more uniform interior surface than could be obtained otherwise." Paragraph [0137] in McNeely does not provide *any* guidance or suggestion concerning the use of "backfilling" to form a channel having appellants' claimed depths of from about 1 to about 10 micrometers. As appellants explained to the examiner and in their briefing to the Board, McNeely paragraph [0084] unequivocally states that 15 micron chambers are preferable and that that "reducing the volume by reducing the chamber height *causes problems* if the height goes below about a certain height." Thus, while the disclosure of "backfilling" in McNeely [0137] may address the problem of surface roughness, that paragraph says nothing about using backfilling to produce chambers having

appellants' claimed depths of from about 1 to about 10 micrometers. If the express warnings in McNeely paragraph [0084] concerning the problems presented by shallow channel depth are given any weight, McNeely's disclosure in paragraph [0137] concerning backfilling cannot be read as describing the formation of channels having depths of less than 15 micrometers. *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (reversing conclusion of obviousness where district court "disregard[ed] disclosures in the references that diverge from and teach away from the invention at hand"). Accordingly, because the Board's application of McNeely misapprehends appellants' arguments and McNeely's own teachings, the Board's decision should be reconsidered and the case be reheard.

D. The Board Misapprehended Appellants' Objective Evidence of Nonobviousness

In its decision, the Board dismissed appellants' objective evidence of nonobviousness on the ground that appellants' evidence "fails to compare the claimed invention with the closest prior art" (Op. at 7). The Board's finding, however, overlooks that appellants have presented sufficient evidence of superior performance to overcome a *prima facie* case of obviousness.

First, the Board suggests that appellants' evidence warrants no weight because "it fails to compare the claimed invention with the closest prior art" (Op. at 7). This suggestion is misplaced, as the MPEP imposes no express requirement on patent applicants to compare their invention with the closest prior art. *Cf.* MPEP § 716.02(b).

Applicants may establish nonobviousness by comparing the claimed invention with prior art that is commensurate in scope with the claims. MPEP § 716.02(b). In the present case, appellants presented evidence (March 25, 2008 Declaration of Jay West at ¶ 7; Exhibit B to West Declaration at bottom image) showing significant improvement over an "existing alternative" product that, like the claimed invention, operates by hybridizing probes to targets. *See* MPEP § 716.02(e) (applicants may compare claimed invention with devices "more closely related" to the invention than the prior art relied upon by the examiner). Here, appellants have compared their hybridization-detection system to an existing, alternative hybridization-detection system, and such a comparison between an invention and an existing device that performs the same function is plainly entitled to evidentiary weight. MPEP § 716.02(e). Because both the Board and the examiner overlooked the significance of this

comparison, the Board's decision on this issue should be reconsidered and the case be reheard.

Second, appellants have demonstrated the claimed invention's superior performance over the cited prior art. Appellants' evidence demonstrated that the claimed invention achieves probe hybridization in only about 5 minutes (Declaration of Jay West at ¶ 7; Exhibit B to West Declaration at bottom image). The cited McNeely reference, however, states the technology described in that reference requires "**overnight**" incubation (McNeely at [0153], emphasis added) to achieve hybridization.¹ Making the reasonable assumption that the term "overnight" means at a minimum 8 hours, the claimed invention achieves hybridization **96 times** (i.e., 8 hours x 60 minutes / 5 minutes) faster than the cited prior art.² Given this indirect comparison between the claimed invention with the cited prior art, the Board's suggestion that appellants' evidence is somehow deficient misapprehends the evidence.

Contrary to the examiner's and Board's conclusions, appellants' evidence of nonobviousness in the form of Exhibit B of the West declaration and the available indirect comparison provided by McNeely and the West declaration are entitled to weight. Thus, under the *Oetiker* standard of review, the Board must take a step back and independently weigh the examiner's evidence – here, the statement of the rejection in the Examiner's Answer, without any modification by the Board – with appellants' evidence including the West declaration and reading McNeely as a whole. It is believed when such a weighing is objectively performed without any deference to the examiner or presumption of examiner correctness, the most reasonable conclusion is that the claimed subject matter as a whole would have been nonobvious.

¹ Appellants note that instead of accepting the statement in McNeely paragraph [0153] that hybridization requires "overnight" incubation, the examiner suggested that "[hybridization] could be completed within an hour and just sit there for the rest of the night" (Answer at 29). As appellants explained at page 5 of their Reply Brief, however, the examiner's speculation concerning the true performance of the McNeely reference conflicts with the Federal Circuit's rule that "obviousness cannot be predicated on what is unknown." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

² The Board's statement that "Appellants do not state that the McNeely device was, in fact, one of the devices compared in the West Declaration or shown in Exhibit B" is beside the point. Exhibit B provides a favorable comparison with an available device having the same functionality. As argued, the record contains an indirect comparison with the McNeely device that must be given weight. Neither the examiner nor the Board cite to any requirement that appellants must provide a direct comparison with the McNeely device or that indirect comparisons are not entitled to weight.

Accordingly, because the Board's decision rests on misapprehending appellants' evidence, the Board's March 1, 2011 decision should be reconsidered and reheard.

III. REQUESTED RELIEF

As set forth above, the Board's decision misapprehended appellants' arguments and evidence. Accordingly, this case should be reheard pursuant to 37 C.F.R. § 41.52.

In the event the Board sustains the final rejections of appellants' claims based on the grounds set forth in the March 1, 2011 decision, appellants note that the Board's March 1, 2011 decision is based on a prior art interpretation that differs from that on which the examiner relied, which implicitly establishes that the examiner's earlier rejections are *not* supported by the examiner's interpretation of the prior art.

The Federal Circuit in *In re De Blauwe*, 736 F.2d 699 (Fed. Cir. 1984), stated that where the Office advances "a position or rationale new to the proceedings, an applicant *must* be afforded an opportunity to respond to that position or rationale by submission of contradicting evidence." *Id.* at 706 n.9 (emphasis added); *see also Hyatt v. Dudas*, 551 F.3d 1307, 1312–13 (Fed. Cir. 2008) ("a 'ground of rejection' ... is not merely the statutory requirement for patentability that a claim fails to meet but also the precise reason why the claim fails that requirement"). As explained above, the Board has advanced a new rationale in this case and has substantially varied from the "precise reason[s]" advanced by the examiner. Accordingly, if the Board maintains the final rejections of appellants' claims, the Board is requested to *reverse* the examiner's rejections and enter the Board's own new rejections in the first instance under 37 C.F.R. § 41.50(b).

The request to reverse the examiner's rejection is not an academic exercise, as appellants are entitled to patent term adjustment ("PTA") for "appellate review by the Board of Patent Appeals and Interferences....in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability" 35 U.S.C. § 154(b)(C)(2)(iii). Thus, it is imperative that the Board base its decision to affirm or reverse a rejection solely on the facts and reasons provided by the examiner in the statement of the rejection appearing in the Examiner's Answer. If the Board cannot affirm a rejection on that basis, it must reverse the rejection and provide appellants their statutory PTA. As provided by 37 CFR § 41.50(b), if the Board is aware of another ground of rejection which, as here, can be based upon the same references relied upon by the examiner but with specific reasons that differ from those relied upon by the examiner, the proper course of action is for the

Board to institute a new ground of rejection under the provisions of that rule and not to “backfill” the examiner’s facts and reasons and label the new ground of rejection an “affirmance.”

IV. CONCLUSION

For all of the foregoing reasons, the Board should rehear the present appeal and reverse the extant rejections.

Respectfully submitted,

Date: April 29, 2011

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